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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,547	11/16/2005	Chaitan Khosla	STAN-258US5	3888

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
05/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,547	KHOSLA ET AL.	
	Examiner	Art Unit	
	JACOB CHEU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24 and 29-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24 and 29-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/19/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Applicant's amendment filed on 3/19/2009 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-22, 25-28 have been cancelled.

2. Claims 29-38 have been added to the instant application.

3. Claims 23-24, 29-38 are pending.

4. Currently, claims 23-24, 29-38 are under examination.

5. The specification and claims 23-24 have been amended accordingly as suggested by the previous Office Action.

6. The rejections under Anderson or Arentz-Hazen et al. references are withdrawn because both references do not specifically teach making antibodies. However, since such technique is a routine practice in the field, Examiner now cites Campbell (see below) for the prima facie obviousness. Accordingly, a new ground of rejection is set forth in this Office Action.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 36-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The conjugates of tissue transglutaminase with SEQ ID No. 12 or its deamidated counterpart cannot be found in the specification. Applicant is invited to point out the support to Examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (WO 03104273) in view of Campbell (section 1.3.4. page 29; Monoclonal Antibody Technology (1984) Elsevier Science Publishers).

Anderson et al. teach a method of diagnosing celiac Sprue disease. Anderson et al. teach detecting polypeptide refractory to digestion which then causes such disease. The polypeptides include PQPQLPYPQ (A2), or PYPQPQLYP (A3) (See page 71, Example

14). Although Anderson et al. do not explicitly teach producing antibody (using hybridom cell line) against these polypeptide, it would have been obvious to one ordinary skill in the art to make antibodies once the antigen has been isolated as taught by Lewicki et al. (Col. 3, line 62-68). Furthermore, *Board of Patent Appeals and interferences* has taken the position that once an antigen has been isolated and sequenced, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990). It is also noted that SEQ ID No. 12 encompasses the above mentioned peptide because Anderson et al. consider these peptides as epitopes. Therefore, if the antibodies can detect PQPQLPYPQ (A2), or PYPQPQLYP (A3), then the antibodies can also specifically bind to SEQ ID NO. 12.

Furthermore, Campbell teaches that *"it is customary now for any group working on a macromolecule*
to both clone the genes coding for it and make monoclonal antibodies to it- sometimes without a clear objective for their application." (See ch. 1, section 1.3.4. page 29).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the conventional method of producing antibody as suggested by Campbell once the peptide of interest is available as taught by Anderson et al. since it is considered a routine "customary practice" in the art to make specific monoclonal antibody recognizing the particular peptides.

1. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arentz-Hansen et al. in view of Campbell.

Arentz-Hansen et al. study Celiac Sprue disease. Arentz-Hansen et al. study several alpha-gliadins for the CD412/CD387 recognition. Arentz-Hansen et al. found out one particular peptide, alpha 2 (62-75) PQPQLPYPQPQLPY, has particular function to stimulate T cell recognition (See Table II; page 606). Such 14-mer peptide is

encompassed within SEQ ID NO. 12. Similarly, as discussed above, it would have been obvious to produce antibody when the antigen is identified and characterized.

2. Claims 23-24, 29-35, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausch et al. (US 7303871) in view of Campbell.

Hausch et al. disclose a glutenase resistance peptide SEQ ID No. 12. Note, the priority of this application is found support in the provisional application No. 60380761, particularly in claim 38, the third polypeptide (33 mer). As has been discussed before, under Campbell, it would have been obvious to manufacture monoclonal antibody cell line or polyclonal antibody against such peptide. Note, Hausch et al. also teaches deamination on peptides (see page 32).

Conclusion

3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641